

## **REMARKS**

### **I. STATUS OF THE CLAIMS AND SUPPORT FOR THE CLAIM AMENDMENTS**

Upon entry of the above amendment, claims 25, 27, 30-33, and 36 are all the claims pending in the application. Applicant has canceled 26, 28-29, 32, and 34-35 and has also amended 25, 30, 31, and 36 to correct typographical errors and/or to better capture the envisioned commercial embodiments. Support for the claim amendment can be found throughout the specification and originally filed claims. Specifically, support for the current claim amendment can be found in at least paragraphs [0124]-[0126] and [0129] of U.S. Published Application No. 2005/0106695. Accordingly, the amendments to claims do not introduce new matter.

### **II. RESPONSE TO OFFICE ACTION OF 16 NOVEMBER 2007**

#### **A. OBJECTIONS TO THE CLAIMS**

Applicant has amended the claims per the Examiner's suggestion.

#### **B. CLAIM REJECTIONS**

##### **1. Enablement**

The Office Action of 16 November 2007 rejected claims 25-36 under 35 U.S.C. 112, first paragraph, because the specification allegedly fails to "enable any person skilled in the art to which it pertains ... to make and/or use the invention commensurate in scope with these claims." *Office Action of 16 November 2007*, page 3. Specifically, the Office Action states that "the specification while being enabling for a method of inhibiting apoptosis in a cell in vitro, does not reasonably provide enablement ... for a method of inhibiting apoptosis in vivo."... *Office Action of 16 November 2007*, page 3. Applicant asserts that the claim amendments render moot the enablement rejection. Nonetheless, Applicant provides the following comments that illustrate that the specification enables the full scope of the presently claimed invention.

In making the rejection, the Office Action states that “[t]he invention is complex because it uses a peptide that binds to a plethora of protein targets with reasonably the same affinity ... .” *Office Action of 16 November 2007*, page 4. Even assuming *arguendo* that the Office Action is correct in making the assertion that the “invention is complex,” Applicant assert that this ability to potentially effect other molecules is irrelevant to the claimed invention. Specifically, the invention does not claim that the peptides only inhibit the binding of MKK7 to IB1. Rather, the presently claimed invention is directed towards methods of inhibiting apoptosis or promoting cell growth in a neuronal cell or pancreatic cell by contacting the cell with a peptide that can inhibit the binding of MKK7 to IB1. The claims do not contain a limitation that the activity of the peptides can only be used for inhibiting MKK7 binding to IB1. Thus, the specification need only teach how to make and use compositions that inhibit the binding of MKK7 to IB1. The specification is replete with support and examples that teach one of skill the art how to assess if the claimed peptides can inhibit the binding of MKK7 to IB1. For example, paragraphs 0123-0126 (Examples 3 and 4) describe assays for measuring the inhibition of MKK7 to IB1, as well as measuring inhibition of cell death.

The Office Action also alleges that “Applicant is using a homogeneous population of cells, which does not accurately reflect the enormous number of potential binding partners to the claimed peptide *in vivo*. Thus, one cannot surmise what the peptides does from *in vitro* data.” *Office Action of 16 November 2007*, page 5. Applicants respectfully disagree with the Office Action’s assertion that the specification does not enable the full scope of the claimed invention with respect to cell type. Applicant, however, has amended the claims to better capture the envisioned commercial embodiments, and Applicant asserts that the claim amendments render moot this particular aspect of the enablement rejection. Again, the specification provides ample support for one of skill the art to determine if the claimed peptides can inhibit the binding of MKK7 to IB1 in pancreatic or neuronal cells.

As a matter of clarification, Applicant points out that the Office Action states that “the Examiner can find not one molecule designed to specifically effect the interaction between an

SH3 domain and its binding protein.” *Office Action of 16 November 2007*, page 5. Applicant points out that the entire specification is directed to molecules designed to interact between an SH3 domain (MKK7) and its binding protein.

Applicant asserts that the specification provides ample guidance to one of skill in the art for making and using the currently claimed invention. Applicants respectfully request reconsideration and withdrawal of the enablement rejection.

## **2. Written Description**

The Office Action of 16 November 2007 rejected claims 10, 13, 18, 21, and 22 under 35 U.S.C. 112, first paragraph, as allegedly “failing to comply with the written description requirements.” *Office Action of 16 November 2007*, page 6. Specifically, the Office Action states that “... ‘capable of binding’ does not require that the variant bind ... [t]herefore there is no real functional limitation to the peptides claimed.” *Office Action of 16 November 2007*, page 6. Without agreeing with the Office Action, Applicant has amended claims 25, 30, 31, and 36 to better capture the envisioned commercial embodiments and asserts that these claim amendments render moot the written description rejection. Specifically, Applicant has amended the claims to indicate that the claimed peptides must possess the ability to inhibit the binding of MKK7 to IB1. Applicant respectfully requests reconsideration and withdrawal of the written description rejection.

**CONCLUSION**

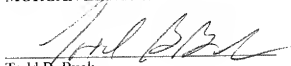
In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 50-0310. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

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